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(71) Applicant *(for all designated States except US)*: IDEC PHARMACEUTICALS CORPORATION [US/US]; 11011 Torreyana Road, San Diego, CA 92121 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: GRILLO-LOPEZ, Antonio, J. [US/US]; P.O. Box 3797, Rancho Santa Fe, CA 92067 (US). LEONARD, John, E. [US/US]; 3440 Camino Alegre, Carlsbad, CA 92009 (US).

(74) Agents: GESS, E., Joseph et al.; Burns, Doane, Swecker & Mathis L.L.P., P.O. Box 1404, Alexandria, VA 22313-1404 (US).

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(54) Title: CHIMERIC ANTI-CD20 ANTIBODY TREATMENT OF PATIENTS RECEIVING BMT OR PBSC TRANSPLANTS

(57) Abstract

The use of a chimeric anti-CD20 antibody, RITUXAN®, as an *in vivo* or *in vitro* purging agent, of patients receiving bone marrow or peripheral blood stem cell transplant during treatment of B-cell-related malignancies, e.g., B-cell lymphomas or leukemias, is disclosed. Such purging may enhance engraftment and/or prevent disease relapse in such patients.

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CHIMERIC ANTI-CD20 ANTIBODY TREATMENT OF PATIENTS RECEIVING BMT OR PBSC TRANSPLANTS

FIELD OF THE INVENTION

The use of an anti-CD20 antibody or a fragment thereof as an *in vitro* or *in vivo* purging agent in patients receiving bone marrow transplant or peripheral blood stem cell transplant is disclosed.

BACKGROUND OF THE INVENTION

The use of antibodies to the CD20 antigen as diagnostic and/or therapeutic agents for B-cell lymphoma has previously been reported. CD20 is a useful marker or target for B-cell lymphomas as this antigen is expressed at very high densities on the surface of malignant B-cells, i.e., B-cells wherein unabated proliferation can lead to B-cell lymphomas.

CD20 or Bp35 is a B-lymphocyte-restricted differentiation antigen that is expressed during early pre-B-cell development and remains until plasma cell differentiation. It is believed by some that the CD20 molecule may regulate a step in the B-cell activation process which is required for cell cycle initiation and differentiation. Moreover, as noted, CD20 is usually expressed at very high levels on neoplastic ("tumor") B-cells.

Previous reported therapies involving anti-CD20 antibodies have involved the administration of a therapeutic anti-CD20 antibody either alone or in conjunction with a second radiolabeled anti-CD20 antibody, or a chemotherapeutic agent.

In fact, the Food and Drug Administration has approved the therapeutic use of one such therapeutic anti-CD20 antibody, RITUXAN®, for use in relapsed and previously treated low-grade non-Hodgkin's lymphoma (NHL).

Also, the use of RITUXAN® in combination with a radiolabeled murine anti-CD20 antibody has been suggested for the treatment of B-cell lymphoma.

However, while anti-CD20 antibodies and, in particular, RITUXAN®, have been reported to be effective for treatment of B-cell lymphomas, such as non-Hodgkin's lymphoma, the treated patients are often subject to disease relapse. Therefore, it would be beneficial if more effective antibody treatments could be developed. More specifically, it would be advantageous if other therapeutic applications of anti-CD20 antibodies were discovered. Also, it would be helpful if current treatment protocols for B-cell lymphoma were improved, which prevented or further reduced disease relapse.

BRIEF DESCRIPTION OF THE INVENTION

Thus, it is an object of the invention to improve the problems of prior treatments of B-cell-related diseases, e.g., B-Cell lymphomas and leukemias, in particular the problem of disease relapse after disease treatment.

More specifically, it is an object of the invention to reduce the incidence of disease relapse in patients with B-cell-related diseases receiving bone marrow or peripheral blood stem cell transplants by the use of an anti-CD20 antibody as an *in vitro* and/or *in vivo* purging agent prior, concurrent, and/or after transplant.

It is an even more specific object of the invention to use RITUXAN® as an *in vitro* and/or *in vivo* purging agent prior, concurrent and/or after bone marrow or peripheral blood stem cell transplant.